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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/675,938 | 09/29/2000 | James E. McShane | FC0807Q1 | 1065 |

24265 7590 05/20/2003

SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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| EXAMINER |
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SHARAREH, SHAHNAM J

| ART UNIT | PAPER NUMBER |
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1617

DATE MAILED: 05/20/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|-----------------------------|------------------------|---------------------|
| Offic Action Summary | Application No. | Applicant(s) |
| | 09/675,938 | MCSHANE, JAMES E. |
| | Examiner | Art Unit |
| | Shahnam Sharareh | 1617 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 16 March 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 21-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 21-31 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ . |

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 10, 2003 has been entered.

Claims 21-31 are pending.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
3. Claims 21-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakane US patent 5,122,418.

Nakane teaches deodorant compositions (see abstract). Nakane teaches compositions comprising micronized zinc oxide and a fragrance. The amounts of zinc oxide used in Nakane falls within the ranges of the instantly claimed compositions (col 10, lines 48-61, examples 35-38). Nakane teaches the use of propellant as an aerosol deodorant spray in amounts of about 70-85% (example 31, 35, 36). Nakane's powder falls within the ranges of 1 to 100 microns wherein the zinc oxide particles have an average size of 0.01-10 microns which is equal to 10-1000 nm (col 5, lines 38-41; col 10, lines 19-22). Nakane further teaches the use of water, C₁-C₃ alcohols such as ethanol (col 10, lines 16-18; col 11, lines 42-44). Nakane does not explicitly teach the combination of zinc oxide, propellant and solvent.

It is well settled in patent law that selection of known material based on its suitability for its intended use supports a *prima facia* obviousness determination. See MPEP 2144.07. "Reading a list and select a known compound to meet known requirements is no more ingenious than selecting the last piece to put in the last opening in a jig-saw puzzle." *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945).

Accordingly, even though Nakane does not explicitly teach a combination of Zinc oxide particles, propellant with a solvent selected from group water and lower alcohols, it would have been obvious to one of ordinary skill in the art at the time of invention to employ a solvent such as water or ethanol, as suggested in Nakane, to perform their own intended use, because as reasoned in *Sinclair*, selecting such compounds to meet known requirement supports *prima facia* obviousness. Further, it would have been

obvious to one of ordinary skill in the art at the time of invention to achieve the desirable concentration of each ingredient by routine experimentation.

4. Claims 21-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lajoie US Patent 5,466,470 in view of Lisboa et al US Patent 5,679,324.

Lajoie discloses co micronized bicarbonate salts and zinc oxide in particles sizes of 0.01 – 1.0 micron (see abstract, col 2, lines 61). Lajoie further teaches the use of zinc oxide powders in his formulations in the same amount and particles sizes as instantly claimed (see col 5, lines 1-13; col 8, lines 4-25). Lajoie also teaches the use of fragrances in his compositions (examples 3-4). Lajoie does not employ a propellant for delivery of his compositions.

Lisboa et al teaches propellant containing topical cosmetic or therapeutic compositions (see abstract). Lisboa suggests that the use of aerosol compositions gaining wide appeal among both men and women as they are easy to use (see col 1, lines 17-40). Lisboa further teaches that the use of propellants in preparing an aerosol formulation containing various cosmetically suitable ingredients is conventional. In fact, Lisboa suggests the addition of various suitable ingredients such as surfactants, thickeners, moisturizers, coolants, emollients and even sunscreen agents of choice such as zinc oxide for their known therapeutic or cosmetic use (see abstract; col 2, lines 40-67; col 3, lines 55-67; col 6, lines 14-67; col 8, lines 11-20).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to add a propellant, such as those taught by Lisboa, to the compositions of Lajoie and formulate an aerosol topical delivery system of Lajoie's

compositions, because one of ordinary skill in the art would have had a reasonable expectation to succeed in formulating aerosolized formulations that are easy to use and are more appealing to the general consumers.

Conclusion

5. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

ss
May 16, 2003


